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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,749	09/21/2001	Thomas E. Borillo	593/005	5029
1473	7590	05/14/2004	EXAMINER	
FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105			BAXTER, JESSICA R	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,749

Applicant(s)

BORILLO ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-35 and 38-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03302004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on March 30, 2004 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 28, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,152,144 to Lesh et al.

Regarding claim 28, Lesh discloses a method comprising the steps of providing a catheterization apparatus comprising: a tube assembly (apparatus 150), said assembly comprising at least an outer tube (shaft 151); a shaft (shaft 174); and a positioning guide (members 155); percutaneously advancing said tube assembly through a blood vessel to establish a passageway to said atrium (Column 3 line 30 – Column 4 line 3); introducing said positioning guide to a location about the ostium of said appendage (FIGS 21 and 22); deploying said positioning guide to engage

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atrial wall portions (FIG. 22); and using said shaft to transport said device through said passageway to a position within said appendage (FIG. 21).

Regarding claims 30 and 31, Lesh discloses that said reversibly expandable structure comprises providing at least a preformed wire configuration (members 155 and Column 13 lines 41-47).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 28-35 and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesh et al. '144 in view of U.S. Patent No. 5,797,960 to Stevens et al.

Regarding claims 28, 29 and 35-38 and 41, Lesh discloses a method comprising the steps of providing a catheterization apparatus comprising: a tube assembly (apparatus 150); a shaft (member 161); and a positioning tube (shaft 174) with a positioning guide member on an end (members 155); percutaneously advancing said tube assembly through a blood vessel to establish a passageway to said atrium (Column 3 line 30 – Column 4 line 3); introducing said positioning guide to a location about the ostium of said appendage (FIGS 21 and 22); deploying said positioning guide to engage atrial wall portions (FIG. 22); and using said shaft to transport said device through said passageway to a position within said appendage (FIG. 21). Lesh does not disclose an outer tube assembly with securement means to engage surface portions of a septum traversed by the outer tube. Stevens teaches that an outer tube with securement means is provided to allow the introduction of instruments for visualization

and intervention through the outer tube and to provide a securement means that prevents leakage of blood (Column 13 lines 24-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube assembly of Lesh with an outer tube in order to facilitate the insertion of instruments into the heart and to seal the opening in the heart from blood leakage.

Regarding claims 30 and 31, Lesh discloses that said reversibly expandable structure comprises providing at least a preformed wire configuration (members 155 and Column 13 lines 41-47).

Regarding claims 32 and 33, Stevens discloses that said positioning guide further comprises providing a positioning guide having a reversibly expandable structure comprising an inflatable balloon (securement means).

Regarding claim 34, Lesh discloses that the step of providing said tube assembly further comprises providing a delivery tube (shaft 151) for advancing said positioning guide through said tube assembly to a location proximate to said appendage (FIG. 21), and wherein said delivery tube retractably extends through said outer tube.

Response to Arguments

4. Applicant's arguments filed March 30, 2004 have been fully considered but they are not persuasive.
5. Applicant argues that the Lesh embodiment of Figures 20-23 is not a device "for implanting anything in an atrial appendage." However, the claim only requires that the device is capable of delivering a device to the atrial appendage. The device of Lesh is capable of delivering a device to the atrial appendage. Therefore, the rejection over Lesh et al. '144 is proper.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



jrB

Jessica R Baxter
Examiner
Art Unit 3731



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